REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 44, 46, 47, 49-51, 53-55, 60, 61 and 88-90 are pending in the present application. Claim 44 has been amended to more particularly point out and distinctly claim the present invention. Support for claims 89 and 90 may be found in the present specification at page 6, line 30, to page 7, line 10.

In the outstanding Official Action mailed May 7, 2003, claims 44, 46, 47, 49-51, 53-55, 60, 61, and 88 were rejected under 35 USC §112, first paragraph, for allegedly being based on an insufficient written description. This rejection is respectfully traversed.

In imposing the rejection, the Official Action contends that the Boyer et al. and Chaperot et al. publications are insufficient to support the existence of the claimed cells.

However, applicants do not rely solely on these articles to support the existence of the claimed cells. Indeed, applicants believe that the present disclosure in and of itself, is sufficient to show one of ordinary skill in the art that applicants were in possession of the claimed invention at the time the application was filed.

Moreover, the publications do isolate mononuclear cells by aphaeresis and culture mononuclear cells in a culture medium

containing chemical ligands having a receptor on the membrane of mononuclear cells. The publications also result in monocyte-derived antigen-presenting cells (MD-APCs) having higher phagocytic properties of formalin fixed yeast and a higher ability for stimulation of allogenic T lymphocytes when compared to monocyte-derived macrophages.

Applicants cite to Boyer et al to show the results of the uptake of the yeast by the claimed MD-APCs. BOYER et al. compared the ability of macrophages and the claimed MD-APCs ability to capture and phagocytose yeast (Figures 2, 3 and 4). In contrast to the macrophages, a large number of yeast were found to be phagocytosed by the claimed MD-APCs. No single macrophage is able to phagocytose more than 15 yeast whereas about 40% of the MD-APCs did (Figure 3).

The present specification also describes a method for determining the stimulating properties of the claimed MD-APCs on allogenic T cells (page 4, lines 20-27). Figures 1a and 1b exhibit results showing superior proliferation stimulators of the claimed MD-APCs compared to monocyte derived macrophages, obtained in the presence of GM-CSF only.

In CHAPEROT et al., monocytes from the same patient were used for producing, for one part, the claimed MD-APCs and, for the other part, macrophages. As to the results, Figure 2 shows a greater ability of MD-APCs to stimulate T cell proliferation than monocytes and macrophages, the level of

response being 3 to 20 fold higher at 0.5/1 APC/T lymphocyte ratio.

Thus, in view of the above, applicants believe that the publications help in one of ordinary skill in the art how to interpret the present disclosure. Indeed, Applicants believe that the present disclosure provides a sufficient written description that shows one of ordinary skill in the art that they were in possession of the claimed invention at the time of filing the application.

In further support of the rejection, the Official Action cites to United States Patent No. 5,851,756 ('756 Patent). In view of the '756 Patent, the Official contends that the culturing of monocytes with GM-CSF for a period of time must result in the generation of dendritic cells.

However, while the '756 Patent may use the same starting material (i.e., cell source), the '756 Patent does not follow the teachings of the present disclosure. For example, while the Official Action cites to Example 1 as evidence that the same starting material is used, Example 1 clearly teaches the separation of adherent cells from nonadherent cells. The '756 Patent does not isolate mononuclear cells by aphaeresis or culture mononuclear cells as set forth in the present disclosure.

As a result, Applicants believe that the '756 Patent is not an appropriate comparison and fails to show or support the

contention by the Patent Office that a distinct cell type is not produced by the present disclosure.

As to the excerpt from *Fundamental Immunology* by Paul, the excerpt shows a cytokine-driven differentiation of a monocyte into a mature dendritic cell. However, the excerpt does not contradict the teachings of the present disclosure. Rather, the excerpt merely provides a generic overview as to the differentiation of a monocyte into a mature dendritic cell. The illustration in the excerpt shows that the precursor cell must first be incubated with GM-CSF and IL-4. Like the '756 patent, the excerpt does not follow the teachings of the present disclosure. For example, the present specification teaches that it is preferable that IL4 not be used in the culture medium used for incubating the cells (pg. 7, lines 1-10).

As a result, applicants believe that the excerpt fails to support the contentions of the Patent Office that the present disclosure does not satisfy the written description requirement.

In imposing the rejection, the Official Action also alleged that the disclosure at page 5, Table 1, Table 2, and Table 3 fail to show that all living cells described in the present disclosure were MD-APCs (see Official Action, page 4, second full paragraph). However, applicants note that the claimed invention does not state that the MD-APCs are in a homogenous population.

Moreover, the Examiner is reminded that an applicant does not have to describe exactly the subject matter claimed; what is required is a sufficient description to show one skilled in the relevant art that the applicant possessed the claimed invention at the time of filing. *Union Vil. Co. of Calif. V. Atlantic Richfield Co.*, 208 F. 3d 989, 54 USPQ2d 1227, (Fed. Cir. 2000), citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). Indeed, upon reviewing the present disclosure, it is clear that applicants describe new antigen-presenting cells, a process for preparing the same in their use of cellular vaccines (present specification, page 1, lines 4-5).

The desired properties and structure of these cells are clearly described in the present disclosure (page 2, lines 6-8; page 2, lines 32-33; page 3, lines 14-37; and page 4, lines 2-28). More importantly, the original claims themselves recite monocyte-derived antigen-presenting cells (MD-APCs). Thus, it is clear to one of ordinary skill in that ordinary skill in the art applicants were possession of the claimed MD-APCS at the time of filing the application.

As a result, applicants believe that the Patent Office fails to meet its burden in showing that one of ordinary skill in the art would not recognize the invention as defined in the claims from the disclosure *In re Voss*, 557 F.2d, 812, 194 USPQ 267 (CCPA 1977).

The outstanding Official Action also stated that it was inappropriate for an applicant to try to describe experiments that were not adequately disclosed in the specification. However, as noted above, it is not necessary that every last detail of an invention be described, by working examples or otherwise. Moreover, a patent specification is not intended to be a production specification. *Ex parte Wolters et al.*, 214 USPQ 735 (POBA 1979); *In re Gay*, 309 F.2d 768, 135 USPQ 311 (CCPA 1962). While the Official Action contends that the description is inadequate to access the value of the asserted experiments, applicants, applicants note that the Official Action fails to provide any evidence or substantiated reasoning that challenges the validity of the date or applicants' interpretation of the date set forth in the application.

Contrary to the assertions of the Official Action, applicants attempt to describe the experiments "after-the-fact" do not comprise an attempt to introduce new matter into the specification. Rather, applicants' explanations of the data and table are only provided to help explain how one of ordinary skill in the art would interpret the present disclosure. As a result, applicants believe that it is improper for the Examiner not to consider applicants' explanation.

The Official Action also contends that only a single combination of histamine and cimetidine are disclosed in the present application. As a result, the Official Action believes

that the breadth of the claims is inappropriate. However, as noted above, the Official Action fails to provide any evidence that would suggest that the breadth of the claims was inappropriate or that the present disclosure fails to satisfy the requirements of 35 USC §112.

Moreover, the Examiner's attention is also directed to new claim 89 which recites, "at least ligand having a receptor on the surface of monocytes is selected from the group consisting of cimetidine and histamine, and IL-13." Thus, although applicants believe that all of the claims are supported by the present disclosure, claims 89 is directed specific ligands as disclosed in the present application.

Thus, in view of the above, applicants believe that claims 44, 46-67, 49-51, 53-55, 60-61, and 88-90 are supported by the present disclosure.

In the outstanding Official Action, claims 44, 46-47, 49-51, 53-55, 60-61, and 88 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that the recitation of "higher phagocytic properties of formalin fixed yeast and higher ability for stimulation of allogenic T lymphocytes" was indefinite. In particular, the Official Action

objected to the term "higher". However, while the recitation may be broad, applicants believe that the recitation is definite to one of ordinary skill in the art. Indeed, the recited properties are compared with the properties exhibited by "monocyte-derived macrophages prepared in the presence of GM-CSF only".

Thus, one of ordinary skill in the art only has to compare the properties of the claimed MD-APCs to monocyte derived macrophages prepared in the presence of GM-CSF only to understand the scope of the claims. As a result, applicants believe that the claimed invention is definite to one of ordinary skill in the art.

As suggested by the Examiner, claim 44 has been amended so that the term "in the present of" has been replaced with the term "in the presence of". Applicants would like to thank the Examiner for his suggestion as to how to overcome this rejection.

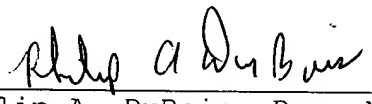
In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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